

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> :  A61F 5/14, A43B 7/22, 13/38	A1	(11) International Publication Number: WO 91/07152 (43) International Publication Date: 30 May 1991 (30.05.91)
<p>(21) International Application Number: PCT/AU90/00543</p> <p>(22) International Filing Date: 9 November 1990 (09.11.90)</p> <p>(30) Priority data: PJ 7446 17 November 1989 (17.11.89) AU</p> <p>(71) Applicant (for all designated States except US): WINPAL PTY. LTD. [AU/AU]; 27 Monro Avenue, Kirrawee, NSW 2232 (AU).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): VASYLI, Phillip, John [AU/AU]; 27 Monro Avenue, Kirrawee, NSW 2232 (AU).</p> <p>(74) Agent: WATERMARK PATENT &amp; TRADEMARK ATTORNEYS; Suite 6, Floor 16, Town Hall House, 456 Kent Street, Sydney, NSW 2000 (AU).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.</p> <p>Published With international search report.</p>
<p>(54) Title: IMPROVEMENTS IN OR RELATING TO ORTHOTIC DEVICES</p> <div data-bbox="397 1281 1128 1606"> </div> <p>(57) Abstract</p> <p>A contoured, moldable orthotic device (1) of about three-quarters the length of the boot or shoe in which it is to fit, wherein the device has an integrally-formed heel cup (2), a longitudinal arch "raise" (3), a metatarsal "raise" (4) and a varus post (⊙). The device is placed in the boot or shoe as far back as it will go and then heated. The patient's boot is introduced into the boot or shoe and the now-pliable orthotic device is molded and otherwise manipulated to the foot.</p>		

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IMPROVEMENTS IN OR RELATING TO ORTHOTIC DEVICESTECHNICAL FIELD

This invention relates to orthotic devices and more particularly to such a device which is able to be molded to a patient's foot, "in situ" in an article of footwear, to give support to, and to control, the osseous structures of the foot.

BACKGROUND ART

So called "orthotic devices" are known, ranging from simple contoured insoles to costly structures integrally incorporated into made-to-order orthopaedic footwear.

Orthopaedic footwear apart, known insertable insole devices as a general rule overlie the whole of the upper surface of the liner of the shoe sole, thus requiring the existence of an extensive range of lengths, widths and even shapes - for example, the court-fit shape in women's dress shoes. These known insoles are usually sold "off the shelf" and provide but indifferent biomechanical control or, if they are fitted to the patient's shoe, the fitting and adjustment time may be quite long. They rarely provide satisfactory bio-mechanical control for, and control of, the osseous structures of the foot and are often made of unyielding materials such as hard plastic or carbon fibre; on the other hand, many resilient molded insoles merely function as shock absorbers.

"Full length" orthotic devices are disclosed in such U.S. Patents as No. 3,895,405 (EDWARDS) in which insoles are molded from an initially flat sheet (see Figures 1 and 2); in No. 3,782,390 (JOHNSON) is taught a method of producing inserts by injecting a curable fluid into a shoe in which is a foot 8; No. 2,760,281 (COSIN) discloses an insole or insert composed of several discrete layers including a "sandwiched" triangular element 15; and No. 2,409,594 (SHERMAN) discloses a corrective foot appliance formed from sheet material which is "capable of becoming relatively permanently set in shape in the course of time when treated with an activator."

U.S. Patent Nos. 4,674,204; 4,232,457; 3,825,017

and 4,522,777, to SULLIVAN, MOSHER, SCRIMA and PETERSON respectively disclose various orthotic insoles having spongy or foam layers.

5 In U.S. Patent No. 2,401,514 (SCHOLL) the inventive concept is a strip of fabric 15 applied to the underside of a thermoplastic resin arch support to prevent it from sliding and squeaking when worn inside a shoe; U.S. Patent No. 4,517,981 (SANTOPIETRO) relates to a substantially flat, three-quarter length orthotic device having no longitudinal arch "raise" or  
10 metatarsal "raise". U.S. Patent No. 4,823,420 (BARTNECK) discloses a contour molded insole, including several layers of material; it is apparently somewhat less than three-quarter length and it is arbitrarily cut off in a straight transverse front edge provided with no metatarsal "raise".

15 Other specifications of interest are U.S. Patent Nos. 2,653,396 (GOTTLIEB); 3,068,872 (BRODY); 3,121,431 (ROSENHAFT); 3,859,740 (KEMP); 3,309,797 (POATIS); 4,216,778 (WEISS); 4,268,980 (GUDAS); 4,346,525 (LARSEN); 4,364,188 (TURNER); 4,463,761 (POIS); 4,520,581 (IRWIN); 4,530,173  
20 (GESINSKY); 4,557,060 (KAWASHIMA); 4,563,787 (DREW); 4,674,201 (WEISS); 4,686,993 (GRUMBINE); 4,702,255 (SCHENKI); 4,756,096 (MAYER); 4,791,736 (PHILLIPS) AND 4,868,945 (DE VETTIGNIS).

#### DISCLOSURE OF INVENTION

25 It is therefore an object of the present invention to overcome or, at least, mitigate certain disadvantages and shortcomings of the prior art by, in a first aspect, the provision of a contoured moldable orthotic device having certain pre-determined shapes and angles and adapted to be inserted into an article of footwear so as to overlies part of  
30 the upper surface of a sole thereof and to be able to be subsequently molded in situ to a patient's foot to thereby give support to, and to control, the osseous structure thereof, the length of said moldable orthotic device being substantially three-quarters of the length of the said article of footwear so  
35 as to underlie the heel bone and to terminate adjacent the head ends of the metatarsal of a said patient's foot; said orthotic

device being formed with an integrally molded heel cup, a longitudinal arch raise, a varus post of about  $4^{\circ}$ , and a metatarsal raise for aligning the heads of the second, third and fourth metatarsals.

5           Ideally, the width of the moldable orthotic device is that distance from the lateral aspect of the head of the fifth metatarsal to the longitudinal bisection of the first and second metatarsals; the arrangement being such that the shaft of the first metatarsal is able to plantarflex during the  
10       propulsive phase of a said patient's foot.

          The terms "raise" and "plantarflex" are well-understood by those familiar with the field of orthotic devices.

          In a second aspect, the present invention may  
15       provide a method for the subsequential in situ molding, to a patient's foot, of a moldable orthotic device, the said method comprising the steps of:-

          (i) inserting said moldable orthotic device into a selected article of footwear;

20       (ii) positioning said device as far to the rear of said article of footwear as it will go, so as to overlies said part of the upper surface of the said sole;

          (iii) heating said device with a stream of air, in a sequence cycle of about five seconds in an "on" mode followed  
25       by about five seconds in an "off" mode, and repeating said cycle until such time as said device has undergone a total heating time of about twenty seconds;

          (iv) fitting said patient's foot into said article of footwear, with the patient seated;

30       (v) palpating the patient's subtalar joint to a neutral position;

          (vi) with the patient standing, putting equal weight on each foot while maintaining the neutral position of the said subtalar joint, pressing medial and lateral edges of  
35       said article of footwear inwards so as to contour the now-warm, moldable orthotic device to the patient's neutral foot

position; and

(vii) allowing the said device to cool.

#### BRIEF DESCRIPTION OF THE DRAWINGS

In order that a better understanding of the present invention may be gained, hereinafter will be described preferred embodiments thereof, by way of example only and with reference to the accompanying drawings in which:-

Figure 1 is a side elevation of the right-hand side of a left-foot moldable orthotic device;

Figure 2 is a bottom plan view;

Figure 3 is a side elevation of the left-hand side of the device;

Figure 4 is a top plan view;

Figure 5 is a frontal top perspective;

Figure 6 is a fragmentary view of the bottom of the heel portion of another embodiment which is provided with a shock-absorbing, spongy "shock dot" insert; and

Figure 7 is a cross-section along line VII-VII of Figure 6, but somewhat exaggerated as regards proportions.

Throughout the drawings, like integers are referenced by the same numeral and, throughout the specification, the adjective "orthotic" is used to qualify "device", instead of the alternatives "orthotic", "orthopodic" or "orthopaedic".

In the drawings there is shown a moldable orthotic device, generally referenced 1, which may well be of such a material as 350 Kg/M<sup>3</sup> density "ETHYL VINYL ACETATE" (E.V.A.) or 220 Kg/M<sup>3</sup> density "ETHYL VINYL ACETATE" (E.V.A.). The specifications of these two materials are as in the following table:-

PROPERTY & TEST METHOD	UNITS	"E.V.A."	"E.V.A."
DENSITY	Kg/M <sup>3</sup>	350	220
HARDNESS (jis type C)	-	74	57
WATER ABSORPTION			
(jis K6767)	gms/cm <sup>3</sup>	<0.002	<0.002
THERMAL CONDUCTIVITY	W/M° C.	0.064	0.055

(astm 578)			
OPERATING TEMPERATURE	Min °C	-70°C	-70°C
	Max °C	70°C	70°C
TENSILE STRENGTH	MPa	3.0	2.0
5 (jis K6767)			
TEAR STRENGTH	N/Cm	170	120
(jis K6767)			
ELONGATION AT BREAK	%	250-300	250-300
(jis K6767)			
COMPRESSION SET	%	< 5	< 5
COMPRESSION DEFLECTION	KPa	950	240
(astm d3575)			

The moldable orthotic device according to the invention may be provided in various geometries, that is to say, in various shapes, as regular adult; women's "court fit"; infants; and youths. Children's size ranges envisaged are, 10 say, 1 - 3; 4 - 6; 7 - 9; 10 - 12; and 13 youths' size 2; in regular and wide fittings: thus, ten 'models' are provided. Also envisaged are adult's sizes 4 - 6; 7 - 9; and 10 - 12; in regular, wide and "court" fittings, nine adult models being provided in this range.

15 Each moldable orthotic device 1 is formed of E.V.A. from a positive cast based on that same configuration as are known rigid devices. The length of the inventive device is substantially three-quarters of the length of the inside of the article of footwear so as to underlie the heel bone, (the 20 calcaneus or os calcis, ), terminating adjacent the heads of the metatarsals, which are those bones between the phalangeal bones and the seven tarsal bones that articulate the foot.

Each orthotic device 1 is formed with an integrally molded heel cup 2, longitudinal arch "raise" 3, and a 25 metatarsal raise 4 for the purpose of aligning the heads of the second, third and fourth metatarsals.

The width of the inventive moldable orthotic device ideally is from the lateral aspect of the fifth metatarsal bone's head to the longitudinal bisection of the first and

second metatarsals. This arrangement permits the shaft of the first metatarsal bone to "plantarflex" during the propulsive phase - that is to say, during walking or running. If necessary, additional wedging and/or other geometric configurations might well be incorporated for the purpose of correcting severe fore-foot, midtarsal and/or rear-foot deformities.

It is contemplated that, initially at least, specifically-trained technical personnel will "custom-mold" the inventive moldable orthotic devices onto existing pre-molded cast templates; however, it is envisaged that a long-term production process will combine in-house "cad/cam" manufacturing procedures with some utilisation of industrial molding techniques.

For certain foot malformations, moldable adjuncts may include 2°, 4°, 6°, or 8° angle adhesive wedges; 4 or 8 mm heel adhesive "raises" and fabric covers for the inventive moldable orthotic devices.

A 4° - angled (or thereabouts) rear foot post - a so-called "varus post" - as indicated by the angle  $\theta$  shown in Figure 3, is in-built to allow for leg curvature and to prevent excess pronation.

In a modification, the pre-molded orthotic device may incorporate a sponge-like, like shock-absorbing insert (highly preferably made of low-density polyurethane foam) which is adapted to cushion that area immediately beneath the heel spur or calcaneus. Such an insert may aptly be termed a "shock dot", or "shock spot". The cushioned area may extend either fully or partially through the full thickness of the orthotic device. Advantageously, the upper surface of the inventive orthotic device may be covered, or sheathed, with a fabric-like outer "skin" - as referenced 6 in Figure 7.

As has been previously stated, the present invention, in its second aspect thereof, may comprise a method, this being for the "in situ" molding, to a patient's foot, of a moldable orthotic device (as has been described above) after



the inventive device has been inserted into an article of footwear so as to overlie part of the upper surface of its sole.

The molding process is as follows:- A moldable orthotic device in accordance with the present invention is inserted into a selected article of footwear, placed as far back as it will go. The device is then heated with a stream of hot air, from a suitable source, using a sequence cycle of about five seconds "on" followed by about five seconds "off". This cycle is repeated until such time as the device has undergone a total heating time of about twenty seconds. The patient is seated and his or her foot is fitted into the boot or shoe; palpate the subtalar joint in the known manner to neutral position. The patient is then required to stand, putting equal weight on each foot, while maintaining the neutral position of the subtalar joint. The medial and lateral edges of the article of footwear are pressed inwards so as to contour the warm moldable orthotic device to the patient's neutral foot position. The device need only to be cooled for perhaps five minutes before the boot or shoe is ready for wearing, perhaps cooled to ambient temperature.

The procedure is then repeated for the other foot, if necessary; however, both articles of footwear of the pair should be worn to ensure equal balance during the molding of each device. If required, fore-foot posts might well be applied to the plantar distal orthotic device's edge subsequent to the molding process. Moreover, it will be realised that an inventive moldable orthotic device may be easily re-molded if the desired result is not initially attained.

The present invention offers several distinct advantages over and above the prior art devices:- greater rear foot control action due to the high and solid heel cup; integrated cushioning "shock dot": correctly contoured for metatarsal correction, longitudinal arch correction, lateral arch correction and sagittal calcaneal correction: greater stability due to the basic solidity of E.V.A. and to the wide

surface rear foot area: in-built varus post, ideally 4°.

Tests have shown that the inventive moldable orthotic device is well able to provide a remedy for common biomechanical problems relating to the foot as listed hereafter:- heel spurs: plantar fasciitis: Metatarsalgia: claw toes: calcaneal apophysitis: archilles tendonitis: shin splints: excess pronation: patella tracking malfunctions: flat feet: and like problems of an orthopaedic nature.

From the abovegoing, it will be appreciated by those skilled in the art that numerous variations and modifications may be made to the invention without materially departing from the spirit and scope thereof, as set out in the following statement of claim.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A contoured moldable orthotic device having certain pre-determined shapes and angles and adapted to be inserted into an article of footwear so as to overlie part of the upper surface of a sole thereof and to be able to be subsequently molded in situ to a patient's foot to thereby give support to, and to control, the osseous structure thereof, the length of said moldable orthotic device being substantially three-quarters of the length of the said article of footwear so as to underlie the heel bone and to terminate adjacent the head ends of the metatarsal of a said patient's foot; said orthotic device being formed with an integrally molded heel cup, a longitudinal arch raise, a varus post of about  $4^{\circ}$  and a metatarsal raise for aligning the heads of the second, third and fourth metatarsals.

2. A moldable orthotic device as claimed in claim 1, wherein the width of said moldable orthotic device is the distance between the lateral aspect of the head of the fifth metatarsal and the longitudinal bisection of the first and second metatarsal; the arrangement being such that the shaft of the first metatarsal is able to plantarflex during the propulsive phase of a said patient's foot.

3. The moldable orthotic device as claimed in claim 1 or claim 2, wherein the said device incorporates a sponge-like, shock-absorbing insert adapted to cushion that area of a patient's foot which is immediately beneath the heel spur thereof.

4. The moldable orthotic device as claimed in claim 3, wherein said cushioned area extends either partially or fully through the full thickness of the moldable orthotic device.

5. The moldable orthotic device as claimed in claim 1

or claim 2, wherein the upper surface of said device is sheathed in a fabric-like outer skin.

6. The moldable orthotic device as claimed in claim 1 or claim 2, formed from ethyl vinyl acetate.

7. A method for the subsequential in situ molding, to a patient's foot, of a moldable orthotic device as claimed in claim 1 or claim 2, the said method comprising the steps of:-

(i) inserting said moldable orthotic device into a selected article of footwear;

(ii) positioning said device as far to the rear of said article of footwear as it will go, so as to overlie said part of the upper surface of the said sole;

(iii) heating said device with a stream of air, in a sequence cycle of about five seconds in an "on" mode followed by about five seconds in an "off" mode, and repeating said cycle until such time as said device has undergone a total heating time of about twenty seconds;

(iv) fitting said patient's foot into said article of footwear, with the patient seated;

(v) palpating the patient's subtalar joint to a neutral position;

(vi) with the patient standing, putting equal weight on each foot while maintaining the neutral position of the said subtalar joint, pressing medial and lateral edges of said article of footwear inwards so as to contour the now-warm, moldable orthotic device to the patient's neutral foot position; and

(vii) allowing the said device to cool.

8. The method as claimed in claim 7, wherein said device is allowed to cool for about five minutes.

9. The method as claimed in claim 7, wherein said device is allowed to cool to ambient temperature.

10. The method as claimed in claim 7, wherein, subsequent to step (vi), fore-foot and/or rear-foot posts are applied to the plantar distal edge of the said moldable orthotic device.

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Fig 1.

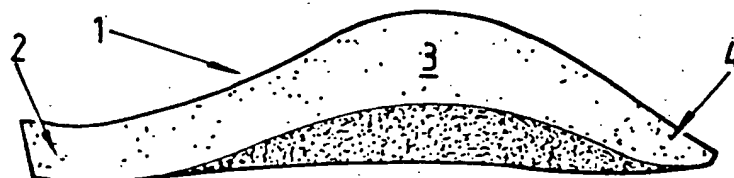


Fig 2.

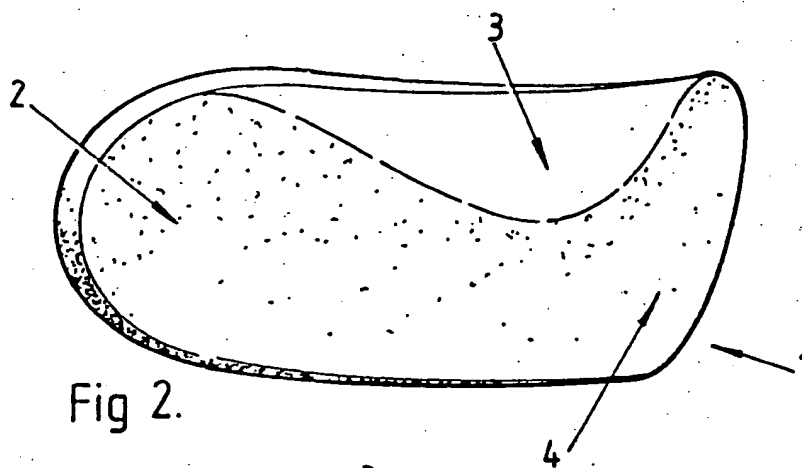


Fig 3.

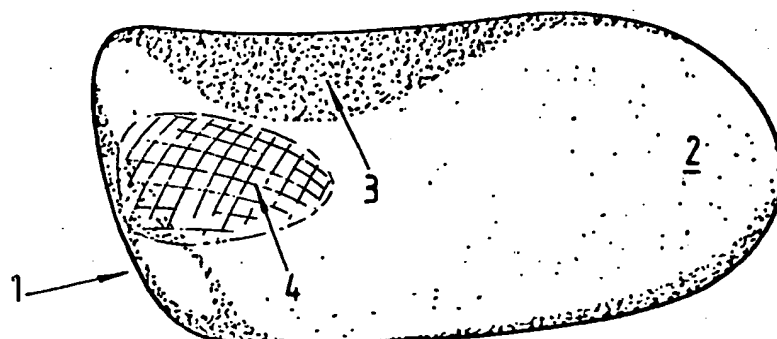
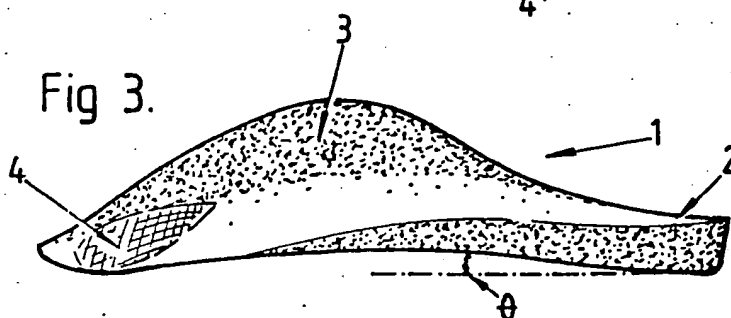
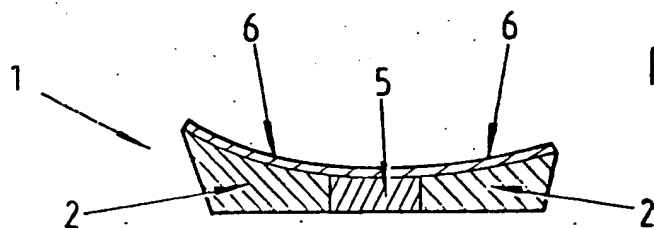
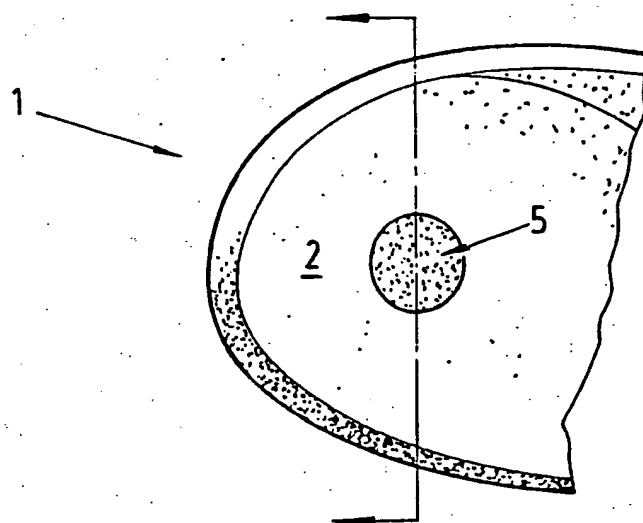
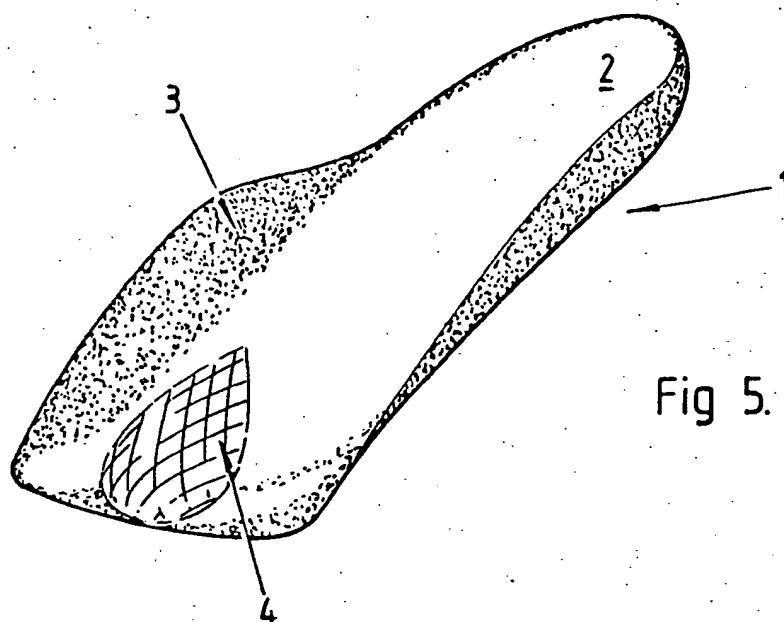
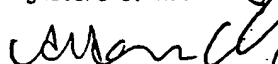


Fig 4.

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<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) 6		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. <sup>5</sup> A61F 5/14, A43B 7/22, 13/38		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched 7		
Classification System	Classification Symbols	
IPC	A61F 5/14, A43B 7/22, 13/38	
Documentation Searched other than Minimum Documentation to the extent that such Documents are Included in the Fields Searched 8		
AU : IPC as above		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> 9		
Category*	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages 12	Relevant to Claim No 13
A	US,A, 4333472 (TAGER) 8 June 1982 (08.06.82)	(1)
A	US,A, 4216778 (WEISS) 12 August 1980 (12.08.80)	(1)
A	US,A, 2313870 (GOLLEN) 16 March 1943 (16.03.43)	(1)
A	AU,A, 40630/85 (KELTSCH et al) 29 August 1985 (29.08.85)	(1)
A	AU,B, 79483/82 (547066) (BAYCROFT) 22 July 1982 (22.07.82)	(1,7-10)
A	AU,B, 12313/43 (121718) (HAMILTON) 25 July 1946 (25.07.46)	(1)
A	EP,A, 118319 (JOHN DREW LIMITED) 12 September 1984 (12.09.84)	(1,7-10)
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<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
1 February 1991 (01.02.91)	11 February 1991	
International Searching Authority	Signature of Authorized Officer	
Australian Patent Office	 A. HENDRICKSON	



ANNEX TO THE INTERNATIONAL SEARCH REPORT ON  
INTERNATIONAL APPLICATION NO. PCT/AU 90/00543

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Members			
EP	118319	GB	8306294	US	4563787
AU	79483/82	CA	1168440	NZ	196010
AU	40630/85	DE	3437627	EP	154170
		JP	61005808	WO	8503624
		DE	3404619	EP	170691
		US	4603541	WO	8503488
US	4216778	CA	1128825	EP	172202
				DE	3405964
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